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10/526,139	02/25/2005	Goro Fujita	09812.0485-00000	6282
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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER CROW, ROBERT THOMAS	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/526,139

Applicant(s)

FUJITA, GORO

Examiner

Robert T. Crow

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE-US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 31 March 2008 in which claim 1 was amended, no claims were canceled, and no new claims were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections under 35 U.S.C. 102(b) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Claims 1-6 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. **This is a new matter rejection necessitated by the amendments.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1, upon which claims 2-6 depend, recites a spacer "module" in lines 6 and 7 of claim 1. While the specification yields a recitation of a spacer **molecule** on the surface, a review of the specification contains no recitation of a "module." Because the

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term "module" encompasses embodiments of a spacer other than a molecule (i.e., an inorganic insulating layer or a nanoparticle, which are not single molecules), the recitation of a "module" constitutes new matter.

Response to Arguments

Applicant's arguments filed 31 March 2008 (i.e., the "Remarks") have been fully considered but they are not persuasive for the reason(s) listed below.

Applicant argues on page 5 of the Remarks that the support for the amendment is found in paragraph 0036 of the published application (US 2005/0255474 A1, published 17 November 2005).

However, as noted above, the referenced paragraph merely refers to a spacer molecule, not a spacer module. Thus, because the scope of the claimed module encompasses embodiments other than a molecule, the amendment is not supported by the specification.

Claim Rejections - 35 USC § 102/103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-6 rejected under 35 U.S.C. 102(b) as anticipated by Iwasaki et al (Japanese Patent Application Publication No 2001-238674, published 9 April 2001) as evidenced by Fodor et al (Science, vol. 251, pages 767-773 (1991)) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Iwasaki et al (Japanese Patent Application Publication No 2001-238674, published 9 April 2001) in view of Fodor et al (Science, vol. 251, pages 767-773 (1991)). Citations of Iwasaki et al are to the machine translation of the document provided by the National Center of Industrial Property Information and Training website http://www.ipdl.ncipi.go.jp/homepg_e.ipdl. The machine translation of the document was provided with the previous Office Action mailed 4 January 2008).

Regarding claim 1, Iwasaki et al teach a bioassay substrate. In a single exemplary embodiment, Iwasaki et al teach the disc-shaped bioassay substrate of Figures 1 and 2, which comprises optically interpretable recorded information in the form of tracking marks 5 and address marks 6 (Description of the Drawings). The disc further comprises a plurality of detection units comprising a data detecting area comprising a reaction area for performing a mutual reaction process between substances to be detected and a target substance; namely, Figure 2 shows the partitioned area of a glass surface 8 following track mark 5 comprising spot 9 (Figure 2, paragraph 0049 of the Detailed Description, and the Description of the Drawings). The area of the glass surface is the reaction area, which further comprises a detection surface for fixing end portions of the substances to be detected in the form of spot 9, to

which DNA molecules are fixed (paragraph 042 and 0049 of the Detailed Description, Figure 2, and the Description of the Drawings). Iwasaki et al further teach a spacer module in the form of a molecule having an amino group on the surface of the detection surface (paragraph 0009). The amino groups do not interfere with the hybridization reaction (i.e., the mutual reaction process). Because the nucleic acids immobilized on the disc are attached to the amino groups on the disc, the molecules bearing the amino groups are the instantly claimed spacer modules.

It is noted that the claim requires "a detection surface for fixing end portions of the substances to be detected." The claim therefore only requires an area for fixing, and does not actually require substances to be fixed to the area. Thus, the limitation "a detection surface for fixing end portions of the substances to be detected" merely recites an intended use of the detection surface.

Iwasaki et al further teach a servo are formed in the detection unit without overlapping the data detecting area; namely, the servo area comprises track mark 5 and address mark 6, which are separate from and non-overlapping with spot 9 (paragraphs Figure 2 and the Description of the Drawings). The servo area and the detection area are arrayed together circumferentially (i.e., as a partition along the die length; paragraph 0049 of the Detailed Description and Figures 1-2). The address marks optically provide information on the data detecting area (paragraph 0064 of the Detailed Description).

The preceding rejection is based on judicial precedent following *In re Fitzgerald*, 205 USPQ 594, because Iwasaki et al are silent with regard to the specific molecule bearing the amino group. However, the molecule bearing the amino group recited in the

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rejection of claim 1 is deemed to be inherent in the teachings of Iwasaki et al, as evidenced by Fodor et al, which is cited by Iwasaki et al (paragraph 0009). Fodor et al teach that the amino group arises from deprotection of linker (i.e., spacer) molecules attached to a substrate (page 767, column 2, first paragraph). The spacer does not interfere with binding of molecules to the immobilized detection molecule (Figure 4). The burden is on Applicant to show that the claimed spacer molecule is either different or non-obvious over that of Iwasaki et al.

Alternatively, Fodor et al teach the spacer has the added advantage of allowing selective deprotection using a mask (page 767, column 2, first paragraph), which allows synthesis of a highly diverse set of chemical products (Abstract). Thus, Fodor et al teach the known technique of using a spacer between the detection surface and an immobilized module that is inactive with respect to mutual reaction processes.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the substrate comprising immobilized detection substances as taught by Iwasaki et al so that the molecules are immobilized with the spacers of Fodor et al as suggested by Iwasaki et al to arrive at the instantly claimed substrate with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a substrate having the added advantage of allowing synthesis of a highly diverse set of chemical products as a result of allowing selective deprotection using a mask as explicitly taught by Fodor et al (Abstract and page 767, column 2, first paragraph). In addition, it would have been obvious to the ordinary artisan that the

known technique of using the spacer molecule of Fodor et al could have been applied to the substrate of Iwasaki et al with predictable results because the known technique of using the spacer molecule of Fodor et al predictably results in stable fixing of the molecule to the detection surface.

Regarding claim 2, the substrate of claim 1 is discussed above. Iwasaki et al teach the reaction area comprises a detection surface on which a surface treatment is performed to as to fix the substances to be detected; namely, the glass surface of the disc is treated with a silane so that DNA probes, which are the substances to be detected, are fixed (paragraph 0080 of the Means).

Regarding claim 3, the substrate of claim 1 is discussed above. Iwasaki et al also teach the substances to be detected and the target substances are nucleotides and the mutual reaction process is hybridization; namely, the disc detects hybridization between fixed DNA probes and target DNA (paragraphs 0015-0020 of the Detailed Description); DNA molecules are nucleotide chains.

Regarding claim 4, the substrate of claim 1 is discussed above. Iwasaki et al further teach the detection units are arrayed along the circumferential direction; namely, the partition comprising a mark and spot is arrayed in a concentric circle, and the partition divisions are carried out along the die-length (i.e., circumference; paragraphs 0049-0050 of the Detailed Description and Figures 1-2).

Regarding claim 5, the substrate of claim 1 is discussed above. Iwasaki et al teach the detection units (i.e., partitions) are arrayed in concentric circles or spiral shapes (paragraph 0050).

Regarding claim 6, the substrate of claim 1 is discussed above. Iwasaki et al also teach the positional information comprises tracking mark 5 and address mark 6, which are separate from a non-overlapping with spot 9 (paragraphs Figure 2 and the Description of the Drawings).

Response to Arguments

Applicant argues on pages 5-6 of the Remarks that Iwasaki et al do not teach the claimed spacer module.

However, as detailed in the rejection presented above, Iwasaki et al do teach a spacer molecule in the form of a molecule bearing an amino group on the detection surface, upon which oligonucleotides are photolithographically synthesized (paragraph 0009). The amino groups do not interfere with the hybridization reaction (i.e., the mutual reaction process). Because the nucleic acids immobilized on the disc are attached to the amino groups on the disc, the molecules bearing the amino groups are the instantly claimed spacer modules.

Conclusion

7. No claim is allowed.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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9. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571)272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert T. Crow/
Examiner, Art Unit 1634

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Examiner
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/Diana B. Johannsen/
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